

and nerves damaged by heart and neuromuscular diseases; that the *Vi-Arthra-M capsules* were offered for energy restoration in detoxification and for the relief of pain associated with rheumatism and arthritis; that the *Pre-Creatine capsules* contained betaine anhydrous and glycocyamine; that the *Neo-Creatine capsules* and the *Neo-Creatine granules* contained betaine anhydrous and glycine; and that the *Vi-Arthra-M capsules* contained betaine, glycocyamine, glucuronolactone, para-aminobenzoic acid, sodium gentisate, and vitamin C. It was alleged further that all of these drugs were new drugs within the meaning of the law and that they may not be introduced into interstate commerce in the absence of an effective new drug application.

The complaint alleged also, with respect to the *Pre-Creatine capsules*, that the defendant submitted a new drug application in the name of Mercury Pharmaceuticals, Inc.; that, in November 1958, this new drug application became effective; and that, on November 27, 1959, this new drug application was suspended on the ground that it contained a number of untrue statements of material facts.

The complaint alleged further that, with respect to the other drugs, no new drug application was filed or ever became effective; that subsequent to November 27, 1959, the defendant continued to introduce all of these new drugs into interstate commerce without having an effective new drug application with respect to any of them; and that the defendant violated the law by causing the introduction and delivery for introduction into interstate commerce of such new drugs since there was no effective new drug application with respect to any of them.

DISPOSITION: On 10-16-61, a consent decree of permanent injunction was entered, enjoining the defendant from causing to be introduced or delivered for introduction into interstate commerce *Pre-Creatine capsules*, *Neo-Creatine capsules*, *Neo-Creatine granules*, *Vi-Arthra-M capsules* or any similar drug, or any other drug containing betaine anhydrous, glycocyamine, glycine, betaine, glucuronolactone, para-aminobenzoic acid, or sodium gentisate, without having an effective new drug application for such drug.

**7002. Pre-Creatine capsules.** (F.D.C. No. 45212. S. No. 23-401 R.)

INFORMATION FILED: 6-12-61, N. Dist. Calif., against Andrew Doty, t/a Creatine Laboratories, Inc., San Francisco, Calif.

SHIPPED: 1-19-60, from San Francisco, Calif., to Kansas City, Mo.

LABEL IN PART: (Btl.) "100 Capsules, PRE-CREATINE, Contains Precursors of Creatine Caution Federal Law Prohibits Dispensing without Prescription Manufactured for Creatine Laboratories, Inc., San Francisco."

CHARGE: 505(a)—when shipped, the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

PLEA: Guilty.

DISPOSITION: 11-6-61. \$300 fine and probation for 2 years.

**7003. Li-Bex with iron and succinylcholine chloride injection.** (F.D.C. No. 47155. S. Nos. 23-357/8 T.)

QUANTITY: 357 vials, each in a plastic case, of *Li-Bex with iron* and 755 vials, each in a plastic case, of *succinylcholine chloride injection*, at Denver, Colo., in possession of Lyle A. Wittney & Co., Inc.

SHIPPED: Between 9-19-61 and 12-14-61, from Decatur and Chicago, Ill.